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Proposed Registration Decision PRD2016-16

Imidacloprid

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Table of Contents

Overview 1
Proposed Registration Decision for Imidacloprid 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Is Imidacloprid? 2
Health Considerations 2
Environmental Considerations 4
Value Considerations 4
Measures to Minimize Risk 4
Next Steps 5
Other Information 5
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
2.0 Methods of Analysis 7
3.0 Impact on Human and Animal Health 7
3.1 Toxicology Summary 7
3.2 Occupational and Residential Risk Assessment 7
4.0 Impact on the Environment 7
4.1 Fate and Behaviour in the Environment 7
4.2 Environmental Risk Characterization 8
4.2.1 Risks to Insect Pollinators 8
4.2.2 Incident Reports 10
5.0 Value 10
6.0 Pest Control Product Policy Considerations 10
6.1 Toxic Substances Management Policy Considerations 10
6.2 Formulants and Contaminants of Health or Environmental Concern 11
7.0 Summary 11
7.1 Human Health and Safety 11
7.2 Environmental Risk 12
7.3 Value 12
8.0 Proposed Regulatory Decision 12
List of Abbreviations 15
Appendix I Tables and Figures 17
Table 1 Maximum residues of imidacloprid and its metabolites measured in various matrices following the injection of imidacloprid in red maple trees at a rate similar to the low rate of Confidor 200 SL 17
Table 2 Toxicity of imidacloprid to bees 17
Table 3 Risk to bees from the consumption of pollen and nectar from trees injected with imidacloprid 18
References 19

Overview

Proposed Registration Decision for Imidacloprid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Confidor 200 SL (Registration Number 29703), containing the active ingredient imidacloprid, in the form of Bay NTN 33893 Technical Insecticide (Registration Number 24468). Confidor 200 SL is intended for systemic control of insect pests on deciduous and coniferous trees.

Although Bay NTN 33893 Technical Insecticide is fully registered for use in Canada, the use of this product for the manufacture of Confidor 200 SL for tree injection is a conditional use. Confidor 200 SL is a conditionally registered product. The detailed review for Bay NTN 33893 Technical Insecticide and Confidor 200 SL can be found in Evaluation Report ERC2011-03, *Confidor 200 SL Containing Imidacloprid*. The current applications were submitted to convert Confidor 200 SL, containing the active ingredient imidacloprid, from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Bay NTN 33893 Technical Insecticide and Confidor 200 SL.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on imidacloprid, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on imidacloprid, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Imidacloprid?

Imidacloprid is a neonicotinoid insecticide that is readily taken up by plants and translocated systemically within the plants. It is active against insects on contact and through ingestion.

Various end-use products containing imidacloprid are currently registered for control of insect pests in turf, on various food crops or on companion animals (dogs or cats). Registered uses on plants include foliar sprays, seed treatments and application to soil for uptake by plant roots.

Health Considerations

Can Approved Uses of Imidacloprid Affect Human Health?

Imidacloprid is unlikely to affect your health when used according to label directions.

Please refer to Evaluation Report ERC2011-03 for the results of the toxicology evaluation for the expansion of use for imidacloprid and the end-use product Confidor 200 SL.

Potential exposure to imidacloprid may occur when handling and applying Confidor 200 SL. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products are used according to label directions.

The active ingredient imidacloprid is of high toxicity when given as a single oral dose to rats. Consequently, the words "Danger Poison" are required on the label for the active ingredient.

Registrant-supplied short-, and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of imidacloprid to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was tremors reflecting effects on the nervous system. There was no indication that the young were more sensitive than the adult animal. The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Occupational Risks from Handling Confidor 200 SL

Occupational risks are not of concern when Confidor 200 SL is used according to the label directions, which include protective measures.

Commercial applicators, including city employees, who mix, load or apply Confidor 200 SL by a pressurized tree trunk injector system have the potential for intermittent dermal and/or inhalation exposure from April to September. Therefore, the label specifies that Confidor 200 SL must only be used with closed application systems and anyone mixing/loading and/or applying Confidor 200 SL, must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves during loading, application, clean-up and repair, and during removal of injection devices from trees. The label also requires that the application sites are not left unattended during the treatment process and applicators must ensure that there is no leakage from the plugged injection holes of host trees after application.

Taking into consideration these label requirements and the expectation of the exposure period for handlers and workers, the risk to these individuals are not of concern.

Potential exposure and risks to bystanders in residential and other non-occupational environments are expected to be negligible when label directions and precautionary measures are followed. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Confidor 200 SL Is Introduced Into the Environment?

Confidor 200 SL is not expected to pose risks of concern to the environment, including insect pollinators.

Because this product is applied as a trunk injection, a lower amount of imidacloprid is released in the environment in comparison to traditional application methods. Risk-reduction measures have been implemented to mitigate potential effects on pollinators visiting the blossoms of treated trees.

When imidacloprid is injected in the tree, it will move primarily to the fast growing parts of the tree such as shoots and leaves. Insect pollinators foraging on the blossoms of treated trees would be exposed to imidacloprid concentrations that are much lower. The risk to insect pollinators is acceptable when use restrictions appearing on the product label are followed.

Value Considerations

What Is the Value of Confidor 200 SL?

Confidor 200 SL provides a pest management tool for important insect pests of trees, including invasive alien species, for which few or no registered alternatives are available.

Confidor 200 SL applied as an injection into the trunks of trees controls foliage-feeding insect pests to levels below those that are damaging to the trees. Wood-boring beetles are more difficult to control and their damage interferes with the uptake of Confidor 200 SL so that it may only provide suppression of these pests.

Confidor 200 SL is the only product registered for bronze birch borer and brown spruce longhorn beetle. It provides an alternative active ingredient for the other pests on the label, of which all but one (woolly apple aphid) have only one or two other registered alternatives. Registration of Confidor 200 SL to control cottony ash psyllid and European elm scale was a priority for Canadian growers. Confidor 200 SL is well suited to integrated pest management because application by trunk injection helps conserve natural enemies of pests as well as other non-target organisms that would be exposed to foliar applications of insecticides.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Confidor 200 SL to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with workers or bystanders coming into direct contact with Confidor 200 SL on the skin, by inhalation, or through unintentional ingestion, anyone loading and applying Confidor 200 SL Systemic Insecticide: 1) must use only closed application systems; 2) must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves during mixing, loading, application, clean-up and repair, and during removal of injection devices from trees; and 3) must ensure that there is no leakage from the plugged predrilled holes of host trees after application. The label also requires that the application sites are not left unattended during the treatment process.

Environment

For trees that may be visited by pollinators, the label restricts the timing of application to after the blooming period in order to reduce the exposure. Measures are also in place to ensure that this product is used appropriately. For example, applications must be made only by individuals holding an appropriate pesticide applicator certificate or license.

Next Steps

Before making a final registration decision on imidacloprid, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on imidacloprid (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Imidacloprid

1.0 The Active Ingredient, Its Properties and Uses

Please refer to ERC2011-03, *Confidor 200 L containing Imidacloprid* for information on the identity of the active ingredient, physical and chemical properties of the active ingredient and end-use product, directions for use and mode of action.

2.0 Methods of Analysis

Please refer to ERC2011-03 for information on the methods for analysis.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Please refer to ERC2011-03 for information on the toxicology of imidacloprid and the end-use product Confidor 200 SL.

3.2 Occupational and Residential Risk Assessment

Please refer to ERC2011-03 for additional information on the occupational and residential risk assessment.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The fate and behaviour of imidacloprid in the environment following a trunk injection has been previously discussed in ERC2011-03. In comparison to other application methods, such as foliar spray, a lower amount of imidacloprid enters the environment when it is injected directly into the trunk of selected trees.

Imidacloprid is a systemic insecticide. Once injected into the trunk of the tree, it is transported upwards in the tree via the xylem. Previously submitted information has shown that imidacloprid injected in trees will move primarily to the fast growing parts of the tree such as the shoots and leaves, but that measurable concentrations are also found in flowers. More recent data have confirmed that concentrations of imidacloprid are highest in leaves and have also shown that levels are much lower in pollen and virtually nil in nectar (leaves > whole flowers > pollen > nectar).

4.2 Environmental Risk Characterization

The risk from imidacloprid tree injections to non-target terrestrial and aquatic organisms has been previously assessed and was found acceptable; please refer to ERC2011-03.

Given the uncertainties identified in the previous risk assessment for insect pollinators, the risk assessment for this group of organisms was revisited in light of recently submitted information and new developments in risk assessment methodology.

4.2.1 Risks to Insect Pollinators

Bees and other insect pollinators may be exposed to imidacloprid residues through the consumption of pollen and nectar from trees injected with Confidor 200 SL. Pollinators would, however, not be exposed through direct contact to the pesticide, as it is injected directly in the tree and, therefore, does not generate any spray droplets or residues on the plant surface.

The honey bee is used as the surrogate species to assess the risk to insect pollinators, and potential risks to both adult bees and bee brood are assessed. In the case of a tree injection, adult foraging bees may be exposed to residues in pollen and nectar during foraging activities. Exposure to other adult bee castes and to brood may also occur if the contaminated pollen and nectar is brought back to the hive.

The levels of imidacloprid to which bees may be exposed are a function of residues in the pollen and nectar as well as food consumption rates. Residue concentrations that were considered for the calculations are shown in Appendix I, Table 1. Low amounts of imidacloprid were measured in pollen and no imidacloprid was detected in nectar. Also, imidacloprid metabolites were not detected in either pollen or nectar. Consumption rates for pollen and nectar vary according to bee caste. To characterize the risk, castes associated with the highest consumption rates were selected to reflect a conservative exposure scenario. For adult bees, food consumption rates for forager bees and nurse bees were selected as they consume the highest amount of nectar and pollen, respectively. For larvae, food consumption rates for 5-day worker bee larvae were selected for the risk assessment.

As part of the risk characterization, the expected exposure is compared to toxicity data from laboratory studies (Appendix I, Table 2). The risk assessment shows that the expected exposure through the consumption of pollen and nectar from treated trees would not be high enough to adversely affect honey bee adults or larvae (Appendix I, Table 3).

The residue data on which the risk assessment was based carries some uncertainty. For example, the study only included one tree species and therefore does not address inter-species variation. In addition, the studied rate was similar to the low rate on the Confidor 200 SL label, but approximately three times lower than the maximum labelled rate for this product. Residue levels may be further underestimated since pollen and nectar were not collected directly from the tree but rather from bees (pollen) or from the hive (nectar). Furthermore, bees did not forage exclusively on treated maple trees (less than 50% of the pollen was from red maple). While this may represent a more realistic exposure scenario, the dilution of residues is a less conservative assumption for the risk assessment. The absence of residues in nectar was also questioned given

that imidacloprid has been shown to translocate to nectar in agricultural crops, including trees (see REV2016-04, *Joint PMRA/USEPA Re-evaluation Update for the Pollinator Risk Assessment of the Neonicotinoid Insecticides*). In addition, mortality of forager bees was observed in incidents where trees were treated with trunk injection (described further below); because forager bees consume mainly nectar, these incidents suggest that imidacloprid in trees can translocate to nectar.

Exploratory calculations intended to provide insight into the relative importance of these uncertainties indicated that even if the concentration of imidacloprid in the pollen and nectar of treated trees was higher than concentrations observed in the submitted study, there would be no larval risk and no acute risk to adult bees. A risk to adult bees following chronic exposure was deemed possible, but only under certain circumstances. For example, if adult bees consumed 100% contaminated pollen and nectar from the treated tree, and residues in nectar were relatively high. Current knowledge on imidacloprid however indicates that residues in nectar are typically much lower than in pollen. Furthermore, all trees in a given area are not expected to be treated, thereby providing opportunities for bees to feed on other non-contaminated food sources. Therefore, when considering the uncertainties with the data, the potential for chronic concern remains low overall. Any potential chronic effects on individual bees are not expected to translate into population level effects.

To reduce exposure, risk reduction measures for Confidor 200 SL include applying only once a year and applying post-bloom on tree species which are attractive to bees. To ensure that the product is used appropriately, applications must be made by individuals holding an appropriate pesticide applicator certificate or license. Furthermore, additional wording has been added to the label to emphasise that Confidor 200 SL is to be used only when needed, as recommended by a tree specialist.

The restriction stipulating that Confidor 200 SL is to be used only in conjunction with a governmental control program was removed from the label. This restriction was added to the label as a precautionary measure during the conditional registration period. It is no longer required now that the data requested under the conditional registration were submitted and the related risk assessment shows low concern for insect pollinators. The removal of this restriction does not increase the risk to bees.

It is also noted that the consumption of guttation water and resinous substances contaminated with imidacloprid were identified as possible routes of exposure during the previous risk assessment on tree injection uses. The concerns associated with the consumption of these materials are lower since current scientific evidence shows that bees rely mainly on nectar and pollen to meet the majority of their nutritional requirements. Research has shown that the collection of guttation water from crops is not comparable to the exposure from nectar and pollen and that, even when honey bees consumed contaminated guttation water, there were no long term colony effects (Pistorius et al., 2011). Furthermore, guttation is not known to occur in mature trees.

4.2.2 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA that include adverse effects to Canadian health and environment. Information on the reporting of incidents can be found in Report a Pesticide Incident on the Pesticides and Pest Management portion of Health Canada's website (http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php).

The PMRA is aware of two incidents related to tree injections and involving bee mortality. Both incidents occurred in the United States and are reported in the United States Environmental Protenction Agency's Ecological Incident Information System. Dead bees were discovered underneath trees that were treated with an imidacloprid tree-injection product. Treated trees were Arbutus, Laurel or Linden trees, which are attractive to bees. In one of the two incidents, samples of leaves, flowers and dead bees contained imidacloprid, which confirms exposure. Although few details are provided, it appears that the application occurred shortly before bloom or during bloom in at least one of the two incidents. It is noted that, in Canada, tree injection applications must be post-bloom on tree species that are attractive to bees.

5.0 Value

Please refer to ERC2011-03 for information on the value of this end-use product.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: that is, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

The TSMP was assessed previously in Regulatory Note REG2001-11, *Imidacloprid* and Regulatory Note R97-01, *Admire*. No new information on imidacloprid was submitted with this data package that would affect the previous assessment.

- Imidacloprid does not meet Track 1 criteria, and is not considered a Track 1 substance.
- Imidacloprid is not expected to form any transformation products that are Track 1 substances.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical, and formulants and contaminants in the end-use product, are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[9] The list is used as described in the PMRA Notice of Intent NOI2005-01[10] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[11] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA previously reached the following conclusions in the Evaluation Report for Confidor 200 SL, ERC2011-03:

- Technical grade imidacloprid and the end-use product Confidor 200 SL do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for imidacloprid is adequate to define the majority of toxic effects that may result from exposure to imidacloprid. In subchronic and chronic studies on laboratory animals, the primary targets were the liver, kidney, thyroid gland, eye and nervous system. There was no evidence of carcinogenicity in rats or mice after long-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies.

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9 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

10 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

11 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

This assessment achieved the target MOE of 100 for occupational exposure scenarios from mixing/loading the formulation in closed application tree injection systems. Although this exposure estimate does not include the applicator exposure, the calculated MOE is considered adequate for mixing/loading/applying, given that the assessment was conducted using conservative assumptions and that exposure for the applicator is likely minimal if a closed application system is used for tree injections. In addition, the occupational exposure and risks from tree injections scenarios are not expected to exceed the exposures and risks from the currently acceptable uses of imidacloprid.

The postapplication exposures for workers and all bystanders are expected to be much lower than the handlers, and considering the postapplication occupational and residential exposures from the currently acceptable uses of imidacloprid, the risks are not of concern.

Loaders and applicators handling Confidor 200 SL and workers re-entering treated areas are not expected to be exposed to levels of Confidor 200 SL that will result in an unacceptable risk when Confidor 200 SL is used according to label directions. The PPE on the product label is adequate to protect workers.

Residential exposure to individuals contacting treated areas is not expected to result in unacceptable risk when Confidor 200 SL is used according to label directions.

7.2 Environmental Risk

The risk assessment for pollinators was revisited in light of new information on the amounts of imidacloprid in the pollen and nectar of treated trees as well as recent updates to the pollinator risk assessment framework. Risk quotients did not exceed the level of concern based on residues measured in pollen and nectar following tree injection. Consideration was given to uncertainties with the residue data, and overall the potential risk to bees was found to be acceptable. To minimize exposure, risk reduction measures for Confidor 200 SL include applying only once a year and applying post-bloom on tree species which are attractive to bees. Measures are also in place to ensure that this product is used appropriately.

7.3 Value

Confidor 200 SL has value for control of various foliage-feeding insect pests of trees, and for control or suppression of certain wood-boring beetles, when injected into the trunks of deciduous or coniferous trees.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Bay NTN 33893 Technical Insecticide and Confidor 200 SL, containing the technical grade active ingredient imidacloprid, for systemic control of insect pests on deciduous and coniferous trees.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
a.i.	active ingredient
bw	body weight
cm	centimetres
d	day
DBH	diameter at breast height
EIIS	USEPA Ecological Incident Information System
g	gram
h	hour(s)
kg	kilogram
LD_{50}	lethal dose 50%
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantitation
mg	milligram
M/L	mixer loader
M/L/A	Mixer/Loader/Applicator
MOE	margin of exposure
n.d.	not detected
ng	nanogram
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PHED	Pesticide Handler Exposure Database
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
RQ	risk quotient
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures

Table 1 Maximum residues of imidacloprid and its metabolites measured in various matrices following the injection of imidacloprid in red maple trees at a rate similar to the low rate of Confidor 200 SL

Compound	Maximum residues (ppb)				
	Leaves	Flowers	Pollen	Nectar	Forager bees
imidacloprid	14963	746	1.5	n.d.	n.d.
6-chloronicotinic acid	n.d.	n.d.	n.d.	n.d.	n.d.
5-hydroxy imidacloprid	441	0.42	n.d.	n.d.	n.d.
imidacloprid-olefin	4493	1.56	n.d.	n.d.	n.d.
imidacloprid-desnitro	n.d.	n.d.	n.d.	n.d.	n.d.
imidacloprid-urea	n.d.	n.d.	n.d.	n.d.	n.d.
imidacloprid-olefin-desnitro	244	n.d.	n.d.	n.d.	n.d.

Residues were measured following one or more yearly injections of imidacloprid at the rate of 79 mg a.i./cm DBH (diameter at breast height), which is similar to the low rate for Confidor 200 SL (61.6 mg a.i./cm DBH), but approximately three times lower than the maximum rate (256 mg a.i./cm DBH).

Depending on how the data were reported for a given matrix, the highest reported value may correspond to an individual sample (flowers, pollen/imidacloprid), a yearly average (leaves/imidacloprid + metabolites) or an overall average across all sampling years (flowers, pollen/metabolites). For averaging, the study author reports to have attributed a value of ½LOD (limit of detection) when trace amounts were detected.

n.d. = not detected. LOD = 1 ppb (imidacloprid), 30 ppb (6-chloronicotinic acid), 25 ppb (5-hydroxy-imidacloprid), 10 ppb (imidacloprid-olefin), 23 ppb (imidacloprid-desnitro), 10 ppb (imidacloprid-urea) and 16 ppb (imidacloprid-olefin-desnitro); LOQ not reported.

Table 2 Toxicity of imidacloprid to bees

Type of test	Test species	Endpoint	Reference
Adult, acute oral	Honey bee	48-h LD_{50} = 3.8 ng a.i./bee	2351184
	Bumble bee	72-h LD_{50} = 170 ng a.i./bee	1086421
Adult, chronic	Honey bee	NOEL = 0.16 ng/bee/day	Boily et al., 2013
Larvae, chronic	Honey bee	NOEL = 1.8 ng/bee/day	2182453

Table 3 Risk to bees from the consumption of pollen and nectar from trees injected with imidacloprid

Caste	Residues in pollen (ng a.i./mg)	Pollen cons. rate (mg/bee/d)	Residues in nectar (ng a.i./mg)	Nectar cons. rate (mg/bee/d)	Oral dose[a] (ng a.i./bee/d)	Type of exposure	Toxicity (ng a.i./bee/d)	RQ
Adult forager bees (nectar)	0.0015	0.041	0	292	6.15×10^{-5}	Acute	3.8	<0.001
						Chronic	0.16	< 0.001
Adult nurse bees	0.0015	9.6	0	140	1.44×10^{-2}	Acute	3.8	0.004
						Chronic	0.16	0.09
Larvae	0.0015	3.6	0	120	5.40×10^{-3}	Chronic	1.8	0.003

a. Oral dose = exposure from pollen + exposure from nectar = [(residue concentration in pollen × pollen consumption rate) + (residue concentration in nectar × nectar consumption rate)].

For adult bees, RQ = Oral dose/Acute oral toxicity. For larvae, the RQ was calculated by comparing residue concentrations directly to the toxicity endpoint.

Shaded cells indicate that the level of concern is exceeded (LOC = 0.4 for acute risk and 1.0 for chronic risk).

References

A. List of Studies/Information Submitted by Registrant

1.0 Environment

PMRA Document Number	References
2373072	2012, The role of pesticides on honey bee health and hive maintenance with an emphasis on the neonicotinoid, imidacloprid, DACO 8.6, 9.9
2351184	1990, The acute oral and contact toxicity to honey bees of compound NTN 33893 technical, DACO 9.2.4.2
2182453	2011, Imidacloprid tech.: Effects of exposure to spiked diet on honeybee larvae (*Apis mellifera carnica*) in an in vitro laboratory testing design, DACO 9.9
2351184	1990, The acute oral and contact toxicity to honey bees of compound NTN 33893 technical, DACO 9.2.4.2

B. Additional Information Considered

i) Published Information

1.0 Environment

2011, Pistorius J., T. Brobyn, P. Campbell, R. Forster, J.-A. Lortsch, F. Marolleau, C. Maus, J. Luckmann, H. Suzuki, K. Wallner, and R. Becker, Assessment of risks to honey bees posed by guttation. 11th International Symposium of the ICP-BR Bee Protection Group, Wageningen (The Netherlands), November 2-4, 2011.

2013, Boily M, Sarrasin B, DeBlois C, Aras P and Chagnon M, Acetylcholinesterase in honey bees (*Apis mellifera*) exposed to neonicotinoids, atrazine and glyphosate: Laboratory and field experiments, Environ Sci Pollut Res 20(8):5603-5614.